ARUP LABORATORIES
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Jonathan R. Genzen, MD, PhD, Chief Medical Officer

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB	5/13/1950
Gender:	Male
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

PD-L1 22C3 IHC with Tumor Proportion Score (TPS) Interpretation, pembrolizumab (KEYTRUDA) and cemiplimab-rwlc (LIBTAYO)

ARUP test code 2013284

PDL1 22C3 by IHC Result	Exp >=50%

This result has been reviewed and approved by [redacted]
M.D., Ph.D. Controls stained appropriately.
2000 Circle of Hope, RM 3100
Salt Lake City, UT 84112

H=High, L=Low, *=Abnormal, C=Critical

INTERPRETIVE INFORMATION: PD-L1 22C3 IHC with Tumor Proportion Score (TPS) Interpretation, pembrolizumab (KEYTRUDA) and cemiplimab-rwlc (LIBTAYO)

PD-L1 protein expression in non-small cell lung cancer (NSCLC) is determined using the Tumor Proportion Score (TPS), which is the percentage of viable tumor cells showing partial or complete membrane staining at any intensity.

Pembrolizumab is approved as a single agent for the first-line and second-line treatment of patients with stage III NSCLC, who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (TPS greater than or equal to 1 percent) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. Pembrolizumab is approved as a single agent for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS greater than or equal to 1 percent) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. Pembrolizumab is approved in combination with pemetrexed and platinum chemotherapy, as first-line treatment of patients with metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor aberrations.
Pembrolizumab is approved in combination with carboplatin and either paclitaxel or paclitaxel protein-bound, as first-line treatment of patients with metastatic squamous NSCLC.

Cemiplimab-rwlc is approved as a single agent for the first-line treatment of patients with advanced NSCLC whose tumors have a TPS of 50 percent or more, as determined by an FDA-approved test. Patients must either have metastatic or locally advanced tumors that are not candidates for surgical resection or definitive chemoradiation, and the tumors must not have EGFR, ALK or ROS1 aberrations.

PDL1 22C3 IHC with Tumor Proportion Score interpretation is an immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) NSCLC specimens using EnVision FLEX visualization system on Autostainer Link 48.

The specimen submitted for testing should contain at least 100 viable tumor cells to be considered adequate for evaluation. This assay is indicated as an aid in identifying NSCLC patients who qualify for treatment with pembrolizumab (KEYTRUDA).

This test is validated and FDA-approved for NSCLC specimens only. For all other specimen types, results should be interpreted with caution and within the appropriate clinical context. Submission of prebaked slides is not recommended, as staining may be affected by over-baking or prolonged time between baking and staining. Submission of specimens fixed in media other than 10 percent neutral buffered formalin is not recommended. The use of this assay on decalcified tissues has not been validated and is not recommended.

Controls were run and performed as expected.

For more information, please refer to practice guidelines published by the National Comprehensive Cancer Network (NCCN) at http://www.nccn.org/professionals/physician_gls/f_guidelines_nojava.asp#site.

Tumor Proportion Score	61-70%

H=High, L=Low, *=Abnormal, C=Critical

Adequacy of Specimen	Adequate
PD-L1 Client Block ID	SN23-5671 A1
PDL1 Tissue Source	FNA LN

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
PDL1 22C3 by IHC Result	23-339-158258	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Tumor Proportion Score	23-339-158258	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Adequacy of Specimen	23-339-158258	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PD-L1 Client Block ID	23-339-158258	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
PDL1 Tissue Source	23-339-158258	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical